

Notice of Allowability

Application No.

10/518,940

Examiner

Shyam Shirali

Applicant(s)

ZHAO ET AL.

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 12/19/05.
2. ☒ The allowed claim(s) is/are ~~10-24~~ 10-24
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 12/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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EXAMINER'S AMENDMENT

Applicant's amendment and arguments filed 12/19/2005 are acknowledged.

In view of the examiner's amendment below, claims ~~10-23~~¹⁰ -24 are allowed.

BC
3/20/06

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Dana Tangren, on March 16, 2006.

The application has been amended as followed:

AMEND claim 10 to recite:

A method of synthesizing alanylglutamine, comprising the steps of:

- 1) form active ester by the reaction of 10 mmol N-terminal protected alanine [[10-30]] 10 to 30 mmol of triphenylphosphine and [[10 -30]] 10 to 30 mmol of hexachloroethane, in organic solvent for 20~~[[min-3]]~~ minutes to 3 hours, and reaction temperature is [[-5 - 30°C]] -5 to 30°C;
- 2) react the active ester obtained from step 1) with [[10-30]] 10 to 30 mmol of glutamine to form N-terminal protected alanylglutamine, in a liquid mixture made by organic solvents and aqueous solution of inorganic base, wherein the volume ratio of organic solvent and aqueous solution of inorganic base is [[0 - 4]] 0-4, reaction temperature is [[5-30°C]] -5 to 30°C and the pH is controlled at 8.5 to 13;

- 3) Acidify the reaction mixture of step 2) with inorganic acid to pH <3.0; and

- 4) remove the N-terminal protecting group to obtain alanylglutamine.

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AMEND steps 1-3 of claim 11 to recite:

The method of synthesizing alanylglutamine according to claim 10, wherein:

1) forms an active ester by the reaction of 10 mmol of N-terminal protected alanine, [[5-20]] 15 to 20 mmol of triphenylphosphine and [[15 – 20]] 15 to 20 mmol of hexachloroethane in organic solvent for [[1.5 – 2]] 1.5 to 2 hours and the reaction temperature is [[0 – 10°C]];

2) react the active ester obtained from step 1) with [[15 – 20]] 15 to 20 mmol of glutamine to form N-terminal protected alanylglutamine, in a liquid mixture made by mixing organic solvent and aqueous solution of inorganic base, wherein the volume ratio of organic solvent and aqueous solution of inorganic base is [[0.5 – 2]] 0.5 to 2, reaction temperature is [[5-10°C]] 5 to 10°C, and pH is controlled at [[9.5-10.5]] 9.5 to 10.5 and

3) acidify the reaction mixture of step 2) to [[pH += 2.0 – 3.0]] a pH of 2.0 to 3.0.

AMEND claim 13 to recite;

The synthesis method of alanylglutamine according to claim 10, wherein: wherein the organic solvent used in step 1) is selected from the group consisted from the group consisting of dichloromethane, toluene, tetrahydrofuran, acetonitrile, and 1,2-dichloroethane.

AMEND claim 14 to recite;

The synthesis method of alanylglutamine according to claim 11, wherein: wherein the organic solvent used in step 1) is selected from the group consisted from the group consisting of dichloromethane, toluene, tetrahydrofuran, acetonitrile, and 1,2-dichloroethane.

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The following is an examiner's statement of reasons for allowance:

The closest prior art, Maziari et. al. (organic letters, 2001, 3 (5) 659). teaches dipeptide synthesis but does not teach or suggest, with any other art or record of dipeptide synthesis and reagents, as instantly claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submission should be clearly labeled "Comments on statement of Reasons for Allowance"

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shyam Shirali whose telephone number is (571)-272-5547. The examiner can normally be reached on 8.00am to 4.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Bruce Campbell can be reached on (571) 272- 0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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